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NOTICE OF ALLOWANCE AND FEE(S) DUE

7590 05/08/2009

Mark S. Graham, Esq. LUEDEKA, NEELY & GRAHAM, P.C. P.O. Box 1871 Knoxville, TX 37901 EXAMINER

STOICA, ELLY GERALD

ART UNIT PAPER NUMBER

1647

DATE MAILED: 05/08/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,285	10/10/2006	Barbara Podobnik	33138-US-PCT	2838

TITLE OF INVENTION: STABLE PHARMACEUTICAL COMPOSITION COMPRISING GRANULOCYTE-COLONY STIMULATING FACTOR

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	08/10/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or <u>Fax</u> (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where ar in m

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P.O. Box 1871	ELY & GRAHAM,			Cer	tificate	of Mailing or Transits) Transmittal is being ficient postage for firs ISSUE FEE address 1) 273-2885, on the day	nission	
Knoxville, TX 3'	7901							(Depositor's name)
								(Signature)
								(Date)
APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR	t	ATTO:	RNEY DOCKET NO.	CONFIRM	MATION NO.
10/577,285 ITLE OF INVENTION	10/10/2006 : STABLE PHARMACE	EUTICAL COMPOSITIO	Barbara Podobnik ON COMPRISING GRAN	ULOCYTE-COLO		3138-US-PCT 'IMULATING FACTO		2838
APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUI	E FEE	TOTAL FEE(S) DUE	Di	ATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810		80	3/10/2009
EXAM	INER	ART UNIT	CLASS-SUBCLASS	;				
STOICA, ELI	LY GERALD	1647	424-085100	.				
FR 1.363). Change of corresponding of the provided responding the provided responsible of the provided responsibl	ence address or indication ondence address (or Char 3/122) attached. ication (or "Fee Address' 2 or more recent) attach	(1) the names of up to or agents OR, alternati (2) the name of a sing registered attorney or 2 registered patent atto listed, no name will be	the names of up to 3 registered patent attorneys agents OR, alternatively, the name of a single firm (having as a member a istered attorneys or agent) and the names of up to egistered patent attorneys or agents. If no name is ed, no name will be printed.					
PLEASE NOTE: Unl recordation as set forth (A) NAME OF ASSIC	ess an assignee is identi n in 37 CFR 3.11. Comp GNEE		THE PATENT (print or ty data will appear on the p T a substitute for filing an (B) RESIDENCE: (CITY	natent. If an assign assignment. Y and STATE OR C	OUNT			
a. The following fee(s) a Issue Fee Publication Fee (N		4b	b. Payment of Fee(s): (Plead A check is enclosed. Payment by credit cate The Director is hereby	ase first reapply an	y prev	iously paid issue fee s	shown abov	ve)
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OTE: The Issue Fee and	s SMALL ENTITY statu d Publication Fee (if requ	ired) will not be accepted	b. Applicant is no lor	-				
terest as shown by the r	records of the United Sta	tes Patent and Trademark	Office.					
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his collection of inform n application. Confident ubmitting the completed his form and/or suggesti ox 1450, Alexandria, V lexandria, Virginia 223	iality is governed by 35 I application form to the ons for reducing this bur irginia 22313-1450. DO	FR 1.311. The informatic U.S.C. 122 and 37 CFR USPTO. Time will vary den, should be sent to the NOT SEND FEES OR (on is required to obtain or 1.14. This collection is es depending upon the indi e Chief Information Offic COMPLETED FORMS T	retain a benefit by t timated to take 12 r vidual case. Any co er, U.S. Patent and O THIS ADDRESS	he publ minutes mment Traden S. SENI	ic which is to file (and to complete, includin s on the amount of tir nark Office, U.S. Depa D TO: Commissioner f	by the USI g gathering ne you requ rtment of C or Patents,	PTO to process), preparing, and ire to complete Commerce, P.O. P.O. Box 1450,

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10/577,285 10/10/2006		Barbara Podobnik	33138-US-PCT	2838	
75	90 05/08/2009	EXAMINER			
Mark S. Graham,	Esq.	STOICA, ELLY GERALD			
	Y & GRAHAM, P.C.	ART UNIT	PAPER NUMBER		
P.O. Box 1871 Knoxville, TX 379	01		1647 DATE MAILED: 05/08/200	9	

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

	Application No.	Applicant(s)					
	10/577,285	PODOBNIK ET AL.					
Notice of Allowability	Examiner	Art Unit					
	ELLY-GERALD STOICA	1647					
	ELLT-GERALD STOICA	1047					
The MAILING DATE of this communication apperature All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RI of the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAINS) CLOSED in this or other appropriate communica GHTS . This application is subje	application. If not included tion will be mailed in due course. THIS					
1. This communication is responsive to <u>04/29/2009</u> .							
2. The allowed claim(s) is/are <u>1-3,6-15 and 19-24</u> .							
 3. ☐ Acknowledgment is made of a claim for foreign priority ur a) ☐ All b) ☐ Some* c) ☐ None of the: 1. ☐ Certified copies of the priority documents have 							
□ Certified copies of the priority documents have □ Certified copies of the priority documents have							
3. ☐ Copies of the certified copies of the priority do							
International Bureau (PCT Rule 17.2(a)).	differite flave been received in t	me national stage application from the					
* Certified copies not received:							
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.							
4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.							
5. CORRECTED DRAWINGS (as "replacement sheets") mus	et be submitted.						
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached							
1) ☐ hereto or 2) ☐ to Paper No./Mail Date							
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date							
Identifying indicia such as the application number (see 37 CFR 1 each sheet. Replacement sheet(s) should be labeled as such in t							
6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.							
Attachment(s) 1. ☐ Notice of References Cited (PTO-892)	5. ☐ Notice of Inform	al Patant Application					
 Induce of References Cited (PTO-092) Induce of References Cited (PTO-	6. ☐ Interview Summ	• •					
	Paper No./Mail	Date					
3. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date	7. ☐ Examiner's Ame	endment Comment					
4. Examiner's Comment Regarding Requirement for Deposit of Biological Material	_	ement of Reasons for Allowance					
	9.						

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REASONS FOR ALLOWANCE

1. The following is an examiner's statement of reasons for allowance: on 04/28/2009 Examiner asked the Applicant's representative, Mr. David J. Gonce to clarify the meaning of the recitation "stable" in the pending claims. In the remarks submitted on 02/25/2009, Applicant amended the claims and persuasively argued against the previous rejections of claims 1-3, 6-15 and 19-20. Since the only hurdle for allowing the claims was the clarification of the meaning of the recitation "stable" in the claims, Applicant submitted a supplemental amendment on 04/29/2009 which clarifies the term and is consistent with the specification. Accordingly the claims 1-3, 6-15, 19-24, as presented on 04/29/2009 amendment are allowed. The previous provisional obviousness-type double patenting rejection of claims 1-3 and 8-11 over claims 1-10 of the copending Application 10/583157 is withdrawn since the claims of the instant Application are allowed and the Application 10/583157 is still pending a response to the non-final rejection.

2. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLY-GERALD STOICA whose telephone number is (571)272-9941. The examiner can normally be reached on 9:00-18:30 M-Th and 9:00-18:30 alternate F.

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Art Unit: 1647

273-8300.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lorraine Spector, Ph.D.

/Lorraine Spector/

Primary Examiner, Art Unit 1647